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April 22, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

MAY 12 2004

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards™ Digestion Formula*	It contains a proprietary blend of enzymes that break down protein, fat and carbohydrates, and is scientifically formulated to improve the release of nutrients, ensuring the best absorption of beneficial nutrients from food.*	Proprietary Plant Enzyme Blend Protease, Amylase, Lipase, Lactase, Phytase, Cellulase, Sucrase, and Maltase

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: *Robert Doster*

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/22/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

*Michael P. Devereux*

Michael P. Devereux  
Chief Financial Officer

975 0162 LET 14039





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April 23, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

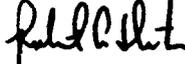
RE Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards™ Digestion Formula*	Digestion Formula contains digestive enzymes that are active in a wide pH range for optimal digestive support.*	Proprietary Plant Enzyme Blend Protease, Amylase, , Lipase, Lactase, Phytase, Cellulase, Sucrase, and Maltase

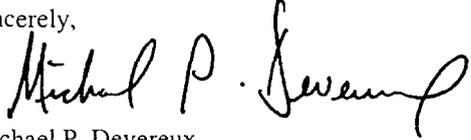
I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By   
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/23/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608

Sincerely,  
  
Michael P. Devereux  
Chief Financial Officer



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April 24, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

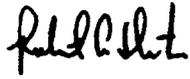
RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards™ Digestion Formula*	Supplemental enzymes may help relieve feelings of bloating and fullness associated with heavy meals, as well as maximizing nutrient absorption.*	Proprietary Plant Enzyme Blend Protease, Amylase, , Lipase, Lactase, Phytase, Cellulase, Sucrase, and Maltase

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:   
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/24/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,  


Michael P. Devereux  
Chief Financial Officer



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April 25, 2004

Office of Nutritional Products, Labeling &  
 Dietary Supplements, HFS 810  
 Center for Food Safety and Applied Nutrition  
 Food and Drug Administration  
 5100 Paint Branch Parkway  
 College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards™ Digestion Formula*	Provides enzymatic support of digestion for proteins, fats and carbohydrates*	Proprietary Plant Enzyme Blend Protease, Amylase, , Lipase, Lactase, Phytase, Cellulase, Sucrase, and Maltase

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:   
 Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/25/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,  
  
 Michael P. Devereux  
 Chief Financial Officer



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April 26, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE. Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards™ Digestion Formula*	Digestion Formula uses different proteases to enhance protein digestion at different pH ranges in the digestive tract.* The blend of these four proteases is active in a pH range of 2-10, meaning that this combination is active in both the stomach and intestine.* This range of enzyme activity enhances protein digestion throughout the digestion system.*	Protease

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_  
Robert Doster

Title. Senior Vice President of Scientific Affairs

Date: 4/26/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608

Sincerely,

A handwritten signature in black ink that reads "Michael P. Devereux". The signature is written in a cursive style with a large, stylized initial "M".

Michael P. Devereux  
Chief Financial Officer



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April 27, 2004

Office of Nutritional Products, Labeling &  
 Dietary Supplements, HFS 810  
 Center for Food Safety and Applied Nutrition  
 Food and Drug Administration  
 5100 Paint Branch Parkway  
 College Park, MD 20740

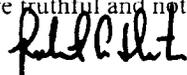
RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards™ Digestion Formula*	Lipases are enzymes activated by bile salts from the pancreas that break down fat during the digestion process.*	Lipase

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:   
 Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/27/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,  


Michael P. Devereux  
 Chief Financial Officer



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**ENZYMATIC THERAPY**  
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April 28, 2004

Office of Nutritional Products, Labeling &  
 Dietary Supplements, HFS 810  
 Center for Food Safety and Applied Nutrition  
 Food and Drug Administration  
 5100 Paint Branch Parkway  
 College Park, MD 20740

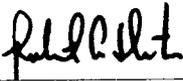
RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards™ Digestion Formula*	Digestion Formula contains two different lipases to enhance fat digestion in different pH ranges of the digestive tract.* The blend of four lipases is active in a pH range of 4-8, meaning that this blend is enzymatically active primarily in the intestine where fat absorption occurs.*	Lipase

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:   
 Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/28/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608

Sincerely,

A handwritten signature in black ink that reads "Michael P. Devereux". The signature is written in a cursive style with a large, prominent initial "M".

Michael P. Devereux  
Chief Financial Officer



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April 29, 2004

Office of Nutritional Products, Labeling &  
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5100 Paint Branch Parkway  
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RE: Label Claims/Disclaimers

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards™ Digestion Formula*	Amylase is an enzyme that breaks down carbohydrates.*	Amylase

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

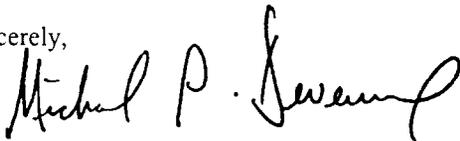
Robert Doster

Title. Senior Vice President of Scientific Affairs

Date: 4/29/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Financial Officer



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April 29, 2004

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RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards™ Digestion Formula*	While carbohydrate intake is limited on a high protein/low-carbohydrate diet, most plans do allow a limited intake. Thus, low-carb dieters will still experience benefits from enzymes that support carbohydrate breakdown.*	Amylase

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are ~~truthful~~ *truthful* and not misleading.

By: Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/29/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

*Michael P. Devereux*  
Michael P. Devereux  
Chief Financial Officer



**INTEGRATIVE THERAPEUTICS INC.**  
 NF Formulas > PhytoPharmica  
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**ENZYMATIC THERAPY**  
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April 29, 2004

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RE: Label Claims/Disclaimers

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards™ Digestion Formula*	The amylase in Digestion Formula is active in a pH range of 4-6, which means it is active in the stomach and intestine.* This kind of enzyme activity breaks down starches throughout the digestive system.*	Amylase

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:   
 Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/29/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
 Chief Financial Officer



**INTEGRATIVE THERAPEUTICS INC.\***  
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**ENZYMATIC THERAPY**  
 INCORPORATED

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April 30, 2004

Office of Nutritional Products, Labeling &  
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 5100 Paint Branch Parkway  
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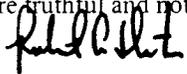
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards™ Digestion Formula*	Cellulase is an enzyme that breaks down cellulose, an indigestible fiber found in many fruits and vegetables, easing its path through the digestive system.* The cellulase in Digestion Formula is active in a pH range of 4-6, making it active in both the stomach and intestine.*	Cellulase

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/30/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
 Chief Financial Officer



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April 30, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards™ Digestion Formula*	Phytase is an enzyme that breaks down carbohydrates.* It specifically breaks down phytates, which are present in the leaves of plants.*	Phytase

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:   
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4-30-04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

  
Michael P. Devereux  
Chief Financial Officer



**INTEGRATIVE THERAPEUTICS INC.\***  
 NF Formulas ♦ PhytoPharmica  
 Tyler Encapsulations ♦ Vitaline Formulas

**ENZYMATIC THERAPY\***  
 &  
**PHYTOPHARMICA\***

**ENZYMATIC THERAPY**  
 INCORPORATED  
*What **Better** feels like™*

9755 SW Commerce Circle, Suite B2  
 Wilsonville, OR 97070  
 P: 503.582.8386 ♦ F: 503.582.0467

825 Challenger Drive, Green Bay, WI 54311-8328  
 P: 920.469.1313 ♦ F: 888.570.6460 (Enzymatic)  
 P: 920.469.9099 ♦ F: 920.469.4418 (Phyto)

April 30, 2004

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards™ Digestion Formula*	The phytase in Digestion Formula is active in a pH range of 5-7, which means that its activity peaks in the intestine.*	Phytase

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_  
 Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/30/04

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Sincerely,

Michael P. Devereux  
 Chief Financial Officer





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May 1, 2004

Office of Nutritional Products, Labeling &  
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Center for Food Safety and Applied Nutrition  
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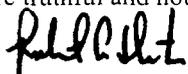
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards™ Digestion Formula*	Supplementing the diet with lactase, amylase, protease, and lipase enzymes will help alleviate the symptoms associated with lactose intolerance.*	Lactase, Sucrase, Maltase

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:   
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/1/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Financial Officer



# ENZYMATIC THERAPY INCORPORATED

*What **Better** feels like.™*

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## ENZYMATIC THERAPY™ & PHYTOPHARMICA™

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May 1, 2004

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards™ Digestion Formula*	Digestion Formula contains three different sugar enzymes to enhance sugar digestion in different pH ranges of the digestive tract.* The blend of three enzymes is active in a pH range of 3-8, meaning that this blend is enzymatically active in both the stomach and intestine.* This range of enzyme activity enhances digestion of these sugars throughout the system.	Lactase, Sucrase, Maltase

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/1/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

A handwritten signature in black ink that reads "Michael P. Devereux". The signature is written in a cursive style with a large, stylized initial "M".

Michael P Devereux  
Chief Financial Officer



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INCORPORATED

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards™ Digestion Formula*	Digestion Formula supports optimal nutrient absorption and digestive health for the low-carb dieter.*	Proprietary Plant Enzyme Blend Protease, Amylase, Lipase, Lactase, Phytase, Cellulase, Sucrase, and Maltase

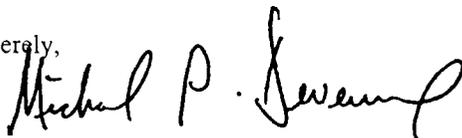
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